

1 Adopt 17 Cal. Code of Regs. section 100304 to read:

2 **§ 100304. Biomedical Materials.**

3 ~~Grantees shall share biomedical materials first created under CIRM funding and~~
4 ~~described in published scientific articles for research purposes in California within 60 days of~~
5 ~~receipt of a request and without bias as to the affiliation of the requestor unless legally~~
6 ~~precluded. Under special circumstances, exceptions to the above are possible with approval by~~
7 ~~CIRM. Alternatively, authors may provide requestors with information on how to reconstruct or~~
8 ~~obtain the material. Such materials are to be shared without cost or at the actual cost of~~
9 ~~providing the material without an allocation of costs for overhead, research, discovery or other~~
10 ~~non-direct costs of providing the material.~~

11 ~~(a) A Grantee shall share Publication-related Biomedical Material that results from~~
12 ~~CIRM-funded Research, for bona fide purposes of research in California. Such materials are to~~
13 ~~be shared without cost to the requestor or at the actual cost of providing the materials without an~~
14 ~~allocation of costs for overhead, research, discovery or other non-direct costs of providing the~~
15 ~~materials.~~

16 ~~(b) A Grantee must share such materials within 60 days of receipt of a written request,~~
17 ~~without bias as to the affiliation of the requestor, unless otherwise prohibited by law.~~

18 ~~(c) CIRM may approve alternatives to this sharing requirement on a showing that:~~

19 ~~(1) the number of sharing requests has become financially onerous for the Grantee;~~

20 ~~(2) a sharing request is in direct conflict with the business of the Grantee;~~

21 ~~(3) the material or its transfer could pose a public health risk; or~~

22 ~~(4) the request is otherwise inappropriate, as determined by CIRM.~~

1 (d) In lieu of sharing as provided herein, a Grantee may provide requestors with the
2 information necessary to reconstruct or obtain identical material.

3 (e) With prior approval from CIRM, a Grantee's obligations under this regulation may
4 cease when the materials are made broadly commercially available.

5 (f) Prior to transferring any Publication-related Biomedical Material, a grantee may
6 require the requestor to execute an industry-standard Material Transfer Agreement restricting the
7 use and dissemination of such materials.

8 (g) A Grantee has no obligation under these regulations to share third party materials
9 described in publications of CIRM-funded Research such as raw materials purchased by the
10 Grantee to develop or synthesize the Publication-related Biomedical Material or other materials
11 covered by third party intellectual property rights, or if the Grantee is legally prohibited from
12 doing so.

13 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
14 Safety Code. Reference: Section 125290.30, Health and Safety Code.